

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/EP2004/004125

International filing date (day/month/year)
19.04.2004

Priority date (day/month/year)
25.04.2003

International Patent Classification (IPC) or both national classification and IPC
B01L3/00, C12Q1/68, G01N1/28

Applicant
NOVEMBER AKTIENGESELLSCHAFT GESELLSCHAFT FÜR ...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

L 25.02.05 FA

VF: 27.12.04

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/004125

Box No. II Priority

1. ☒ The following document has not been furnished:
- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/004125

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-53
Inventive step (IS)	Yes: Claims	
	No: Claims	1-53
Industrial applicability (IA)	Yes: Claims	1-53
	No: Claims	

2. Citations and explanations

see separate sheet

- 1 The following documents are referred to in this communication:
- D1 : US 5 229 297 a (SEABERG LEONARD J ET AL) 20 July 1993
 - D2 : US 4 889 692 a (HOLTZMAN MARC E) 26 December 1989
 - D3 : US 2002/018998 A1 (STEINBISS JOACHIM ET AL) 14 February 2002
 - D4 : US 4 585 623 a (CHANDLER HOWARD M) 29 April 1986
 - D5 : WO 03/031275 a (SIGNATURE BIOSCIENCE INC) 17 April 2003
 - D6 : US 6 197 595 B1 (FODOR STEPHEN P a ET AL) 6 March 2001

Re Item IV

- 2 This Authority considers that there are two inventions covered by the claims indicated as follows:
- I: Claims 1-31 and 33-53 relate to a device comprising two chambers of changeable volume connected by a channel and a connector with flow regulation means connected either to the channel or to one of the chambers and a method using such a device.
- II Claim 32 relates to a kit with a baseplate with a channel and a connector with flow regulation means connected to the channel and a detachable chamber filled with a reagent.
- The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:
- The features shared by the two groups - a chamber, a channel, a connector and flow regulation means - are known from the prior art (see Search Report).
- Beyond these common features, the features of group I (two chambers are linked and their volume is changeable) and of group II (a detachable chamber filled with reagent) are different and solve different problems:
- preventing contamination by providing a closed system without external vacuum source for the first group (see description page 2, lines 27-31 and page 5 from line 30)
 - allowing easier shipping and storing for the second group (see description pages 22-24).

Re Item V

- 3 When compared to any of the documents D1-D3 and D5, the subject-matter of claim 1 is not new (Article 33(2) PCT), because these documents disclose in combination all the features defined in that claim:
- 3.1 Document D1 discloses devices with chambers with pistons (figures 9-14) for reversibly changing their volumes connected by channels and with a sealable inlet port 22 (see c 13, l 63-69) which constitutes a connector with flow regulating means connected to a chamber (eg figure 14). The channel themselves can be

- provided with flow regulating means in form of pinch valves P1-P5 (c 12 , l 19-35).
- 3.2 Document D2 discloses chambers a-F with pistons for reversibly changing their volume, the chambers being connected via channels 36 in a connector which acts as a rotating valve regulating the flow between the chambers
- 3.3 Document D3 discloses in figure 2 an arrangement with two chambers connected by a channel, plungers for changing the volumes of the chambers and a flow regulation means(3-way valve) in the channel linking the two chambers.
- 3.4 Document D5 discloses a collapsible chamber connected to a piston chamber via a piercing needle, the flow being controlled between the two chambers by a septum connected to the collapsible chamber, the septum being thus a means of flow regulation.
- 4.1 When compared to D1, the subject-matter of claim 32 is not new (Article 33(2) PCT), because D1 discloses a device with a base plate with channels and detachable chambers filled with reagents (c 15, l 63-66).
- 4.2 When compared to D4, the subject-matter of claim 32 does not involve an inventive step in the sense of Article 33(3) PCT, because D4 discloses a baseplate with a channel 20. (see figure 2) provided with one way valves 30 and at least a detachable chamber (syringe 40 in figure 1) filled with a sample. Claim 1 differs from D1 by the fact that the chamber is filled with a reagent and not a sample but it would be obvious for a skilled person that such a detachable chamber can be used for feeding a reagent in the device, allowing thus an easier storing and shipping of the reagent.
- 5 As long as it relates to the use of a known device, the subject-matter of claim 32 does not involve an inventive step in the sense of Article 33(3) PCT because the step of moving back and forth a sample solution so that it contacts and binds to a material is known either from D3 (paragraphs 59 and 60) or from D6 (from column 25, line 63).
- 6 The subject-matter of dependent claims 2-31 or 34-53 does not involve an inventive step in the sense of Article 33(3) PCT, because their features have already been employed for the same purpose in similar devices for preparing analytes (see relevant passages cited in the Search Report).